Section 7
Uncertainty Assessment

Uncertainties can arise from several sources in a human health risk assessment including data collection and interpretation, assumptions used to characterize exposures, and toxicity values. To compensate for uncertainty surrounding input variables, conservative assumptions are often made that tend to overestimate rather than underestimate risk. In cases where data are limited, assumptions may be based on professional judgment or subjective estimates that may under or over estimate risks.

7.1 Types of Uncertainty

Three primary sources of uncertainty include:

- Scenario uncertainty
- Parameter uncertainty
- Model uncertainty

Scenario uncertainty results from missing or incomplete information needed to fully define exposure and dose. This uncertainty may include errors or gaps in site characterization, professional judgment, assumptions regarding exposed populations, and steady-state conditions. Sources of parameter uncertainty include measurement and sampling errors, inherent variability in environmental and exposure-related parameters, and the use of generic surrogate data or default assumptions when site-specific data are not available. Parameter uncertainty often leads to model uncertainty. One source of modeling uncertainty is relationship errors, such as errors in correlations among chemical properties or limitations in mathematical expressions used to define environmental processes. Errors due to the use of mathematical or conceptual models as simplified representations of reality are also sources of modeling uncertainty.

Often analysis of uncertainties is divided in "true uncertainty" and "variability." The former is uncertainty due to lack of knowledge of data. Variability is uncertainty due to unresolvable variation in physical, chemical, and biological process, human behavioral patterns, seasonal changes, and data for site characterization. An example of uncertainty in this HHRA involves selection of an exposure frequency for recreational site users. No site-specific information is available and this parameter is based on professional judgment.

An example of variability in this HHRA involves BSAF estimates derived from sediment, TOC, fish fillet, and percent lipid data. These estimates are based on a large amount of site-specific data and are likely to reflect unresolvable variation in this parameter.

These three types of uncertainty have been identified in each of the four parts of this risk assessment: data evaluation, toxicity assessment, exposure assessment, and risk characterization. Uncertainty within each of these components is discussed below.

7.2 Data Evaluation

Uncertainty is present in the data before it is even evaluated for risk assessment. This includes potential sampling bias, errors in laboratory extraction and analysis, and the protocol employed to assess contaminants identified as nondetected. A higher level of confidence is placed on the analytical results. Sampling errors and biases and assumptions for use of nondetect data are almost always more important from uncertainty considerations.

Fish data used to assess risks were collected in 1993 and 1997, and exposed floodplain data were collected in 1994. Because one of the primary sources of PCBs to the River is erosion of material from the riverbanks, and this source is ongoing, levels of PCBs detected in aquatic biota may have not significantly declined in the intervening period. Further, based on the persistence of PCBs, and in the absence removal actions, significant chemical degradation or other means of PCBs is not expected to be significant for floodplain soil. For these reasons, the data used to characterize the risk and hazards associated with ingestion of fish and contact with floodplain soil are deemed appropriate. The use of these data is unlikely to have resulted in a significant underestimation or overestimation of risks and hazards. Still, data are scant or absent for evaluating these assumptions.

Data for two media were deemed inadequate to conduct a quantitative risk evaluation. Turtle consumption is a confirmed exposure pathway for the Kalamazoo River; however, turtle consumption is expected to be less than fish consumption for the majority of people. The risks and hazards associated with fish ingestion provide a conservative estimate of the risks and hazards associated with turtle consumption. The absence of quantified risks and hazards resulting from turtle ingestion likely results in an underestimation of total site risks and hazards.

Air data have not been collected in the immediate vicinity of the River or exposed floodplain areas. Data collected from the Willow Boulevard / A-Site operable unit are not representative of the conditions in the immediate vicinity of the floodplain where soils are unvegetated and prone to entrainment. Concentrations of volatile emissions and particulates above the floodplain soil have been estimated using a simplified model and risks and hazards associated with this pathway were quantified. In the absence of actual air data, whether risks and hazards are underestimated or overestimated cannot be determined.

Air quality above surface water has not been characterized. Inhalation of volatile emissions above surface water was found to be associated with significant risks for the Lower Fox River Site (ThermoRetec 1999). In the absence of actual data and quantitative estimates of risks and hazards for this pathway, total site risks and hazards are likely underestimated.

Data from another site were used to verify that exposures to surface water would not result in significant risks or hazards. Uncertainties associated with these data also apply to the API/PC/KR Site. Since these data have been thoroughly evaluated, uncertainties are assumed to be manageable. More recent data indicate surface water quality data reported in Technical Memorandum 16 – Surface Water Investigation (BB&L) were comparable to data collected from the Lower Fox River.

A concern exists relative to the overall site characterization in terms of whether the appropriate number of samples was taken in the appropriate areas (geospatial relationships of PCBs in sediments and exposed soils). In this risk assessment, mean sediment concentration is a critical input to the HHRA. There are three important issues related to site characterization that could affect the HHRA:

1. Are there adequate data to reliably estimate mean PCB concentrations in surficial sediment?

2. What is the best estimator of mean PCB concentration in sediment?

3. Is bootstrap sampling a valid approach to estimate the sampling distributions of BSAF and RBCs?

These issues are discussed in detail below.

1. Surficial sediment samples from a total of 630 individual locations were used to estimate TOC normalized PCB concentrations at the site. The sample locations were based on 120 transects across the floodplain. The transects show that the concentrations of PCBs vary widely throughout the floodplain. For reach-specific calculations, sample sizes ranged from more than approximately 30 locations to over 160 locations. These data provide adequate sample size to estimate reach-specific and sitewide average PCB concentration.

2. The sample average was used to estimate the spatial average of PCB concentration in surficial sediment. This is justified because the best estimator of the spatial average, among all unbiased linear estimators, is the ordinary block kriging estimator (Cressie 1991, p. 124) and when sample data are either systematically sampled, or uncorrelated, the block kriging estimator simplifies to the usual sample average (i.e., each of the samples receive equal weights). Because the sampling design for instream sediment at the Kalamazoo River is reasonably systematic, and because the data are very weakly autocorrelated, the sample mean is appropriate to estimate the spatial mean of PCB concentration in surface sediments. Although other unbiased estimators are possible, they will be less precise (i.e., less reliable sampling distributions). Using block kriging to estimate spatial means over large areas was first discussed by Journel and Huijbregts

(1973). Kern and Coyle (2000) compare the block kriging and sample average estimators for autocorrelated data and also discuss algorithms and software to estimate the block kriging estimator for large data sets on irregularly shaped areas such as rivers. Most commonly available software packages do not provide such routines.

3. The bootstrap analysis used for the estimation of RBCs, as presented in Section 6, requires that either the sample data are statistically independent in a model based sense (i.e., little or no autocorrelation among sample locations), or that the data were sampled using a randomized design (regardless of the autocorrelation in underlying data), such as a systematic sample with a random starting point or a simple random sample. The sediment data were not collected using a randomized design; however, the design is reasonably close to systematic. Variogram analysis conducted as part of the geostatistical pilot study (Technical Memorandum 10) indicate that sample locations on adjacent transects located one to several thousand feet apart are uncorrelated, and that samples at adjacent locations on a single transect may be very weakly correlated. Given the large sample sizes, the bootstrap algorithm is expected to be robust to the minor departure from assumptions associated with weak spatial dependence. The systematic nature of the sampling design is nearly adequate to justify the bootstrap algorithm even for strongly autocorrelated data. As previously stated, the concentrations of PCBs vary widely across and among transects, justifying the use of bootstrapping.

Other issues related to site characterization such as documentation of extent, estimation of volume, and small-scale patterns in PCB distribution are not likely to affect estimates of human health risk. Data used to prepare this report are adequate both in terms of location and number of samples to estimate risk to human health. EPA is planning to conduct additional sampling in one or two areas of the river to validate the current data set. However, it is unlikely that the results of this sampling effort will substantially affect the final estimates of human health risks and hazards.

7.3 Dose-Response Assessment

The dose-response section involves the estimation of the toxicological effects of a compound on humans usually based upon laboratory animal studies. A potentially significant source of uncertainty occurs when dose-response relationships in humans are derived from animal to human extrapolation. These associates often result from high-dose to low-dose extrapolations as well. Health effects criteria are derived with margins of safety relative to the degree of uncertainty in the value.

Noncancer toxicity values and cancer slope factors have been derived from studies of commercial mixtures. After release into the environment, PCB mixtures change over time so their composition differs from commercial mixtures. Through partitioning, different fractions of the original mixture appear in the air, water, sediment, soil, and biota due to different rates of volatilization, solubility, and adsorption for the congeners. (EPA 1996). Bioaccumulation through the food chain tends to concentrate congeners of higher chlorine content, producing residues that are considerably different from the original aroclors (Cogliano 1998). Both humans and animals retain persistent congeners that are resistant to metabolism and elimination (Oliver and Niimi 1988). Mink fed Great Lakes fish contaminated with PCBs showed liver and reproductive toxicity comparable to mink fed Aroclor 1254 at quantities three times greater (Hornshaw 1983). PCBs tested in the laboratory were not subject to prior selective retention of persistent congeners through the food chain. For exposures through the food chain in most environmental situations, risks are probably higher than those estimated using toxicity values and cancer slope factors based on commercial mixtures (EPA 1996). Risk and hazard estimates for the fish ingestion pathway are likely underestimated. However, congener-specific data are not available to determine the magnitude of effects due to differing environmental fates of various PCB congeners.

7.4 Exposure Assessment

The exposure assessment step involves many assumptions about "typical people" and "typical exposure scenarios" to arrive at an average daily dose. For example, a body weight of 70 kg is used for residents and anglers. Body weight ranges for each individual, so these assumptions likely overestimate or underestimate the true dose that people are likely to receive.

Many exposure factors were chosen to err on the side of protectiveness for human health. Exposure duration, frequency, and time were set at reasonable maximum exposure values. They likely overestimate the exposures that typically occur.

The computation of the exposure point concentration for chemicals in a number of media may have resulted in an overestimate or underestimate of risks and hazards. Averages of site data exposure point concentrations may underestimate risks and hazards for some receptors while use of the maxima from site data exposure point concentration may overestimate risks and hazards for some receptors. Risks and hazards from both types of EPCs are provided in this assessment to try to bracket potential site-related impacts.

Another assumption made in this assessment is that exposure to study chemicals in various media remains constant over time. This suggests there is a nondiminishing source of contamination and that concentrations will remain at present levels for up to 30 years. In reality, soil, sediment, surface, and groundwater migrate. This would produce an exposure significantly less than that calculated in this assessment.

Another assumption made in the assessment is that a target hazard quotient of 1.0 (HI is not applicable, since only one contaminant, PCBs, and one exposure route, ingestion of fish, was considered for angler receptors) was used to calculate the RBC_{fish}. This is a deviation from MDEQ Surface Water Quality Division guidance, which specifies that a hazard index of 0.8 be used to calculate the RBC_{fish}. The MDEQ guidance is intended to be protective of noncancer endpoints based on a relative source contribution factor of 0.8. The relative source contribution factor accounts for the fact that exposures to PCBs may occur from activities other than those which are site-related. The difference between a hazard index of 1.0 and 0.8 is minimal and should not greatly influence the RBC values.

The exposure assumption with the greatest influence on risk and hazard is the fish ingestion rate. Three ingestion rates were chosen to reflect the central tendency sport angler, the high-end sport angler, and cancer risk estimates and hazard quotient estimates. The lowest ingestion rate of 15 grams/person/day, which was used to characterize risks and hazards to the central tendency sport angler, was derived from the Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria and Values (EPA 1995b). This ingestion rate is consistent with the mean ingestion rate for anglers reported in both the Kalamazoo River Angler Survey (MDCH 1998), and Fish Consumption Estimates Based on the 1991-1992 Michigan Sport Anglers Fish Consumption Survey (EPA 1995c). A significant number of anglers ingest greater quantities of fish, therefore, the central tendency estimates under-represent risks and hazards to these individuals. Fish consumption advisories are intended to reduce the ingestion of contaminated fish. If fish consumption advisories are reducing consumption, reported consumption levels will be suppressed from their normal levels (West 1993). Of a total of 1,347 respondents to the Michigan sport anglers consumption study, 46.8 percent reported to have eaten less fish in response to advisory warnings. In the Kalamazoo River Anglers Survey, 25 percent of respondents indicated they would make more trips to the River and fewer to other locations if the River was cleaned up to the point that fish advisories were removed; 15 percent of respondents indicated they would increase fishing in the Kalamazoo River without reducing trips to other bodies of water. This consumption suppression effect can result in an underestimate of risks and hazards for assumed baseline conditions, i.e., in the absence of remediation or risk reduction measures such as fish advisories.

Figures 7-1 and 7-2 show relative impacts of composition of fish (bass only versus a combination of bass and carp) consumed by anglers on cancer risk estimates and hazard quotient estimates for the high-end sport angler. These figures also illustrate the relationship between risk and hazard based on maximum and average fish fillet concentrations. Cancer risks for consumption of both bass and carp (trophic level 4 and 3 fish respectively), show a variety of patterns among different ABSA. For ABSAs 3,4 and 5, 10 and 11, consumption of both bass and carp is associate with significantly higher risk and hazard than consumption of bass only. In contrast, much smaller differences are seen for ABSA 6, 7, and 8. For ABSA 9, Lake Allegan, almost no difference is noted. These results probably reflect variability in data, but could also reflect differences in habitat that produce different levels of exposure for fish in different ABSAs. Data are insufficient to resolve such issues at present.

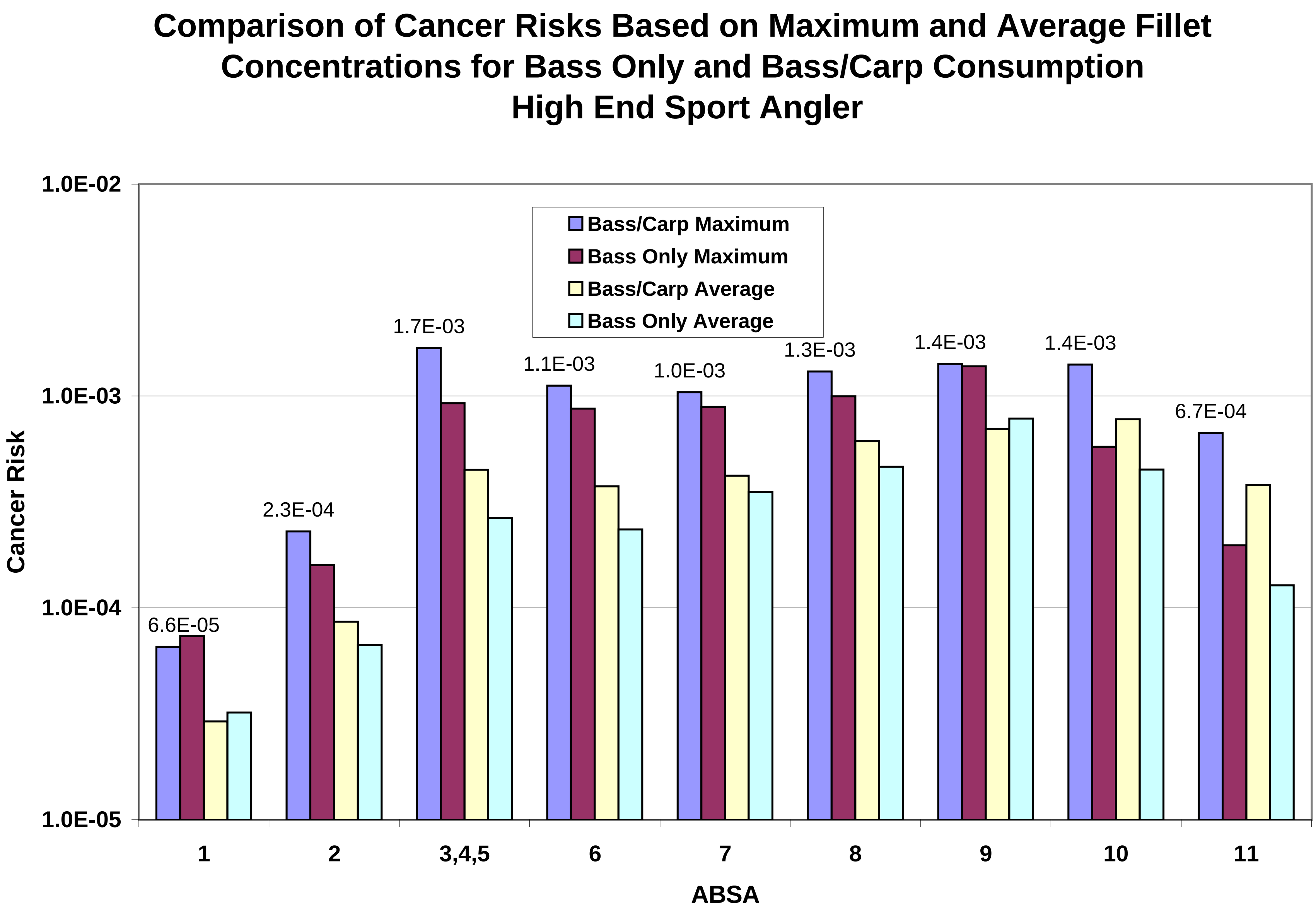

FIGURE 7-1

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Comparison of Hazard Quotients Based on Maximum and Average Fillet Concentrations for Bass Only and Bass/Carp Consumption High End Sport Angler

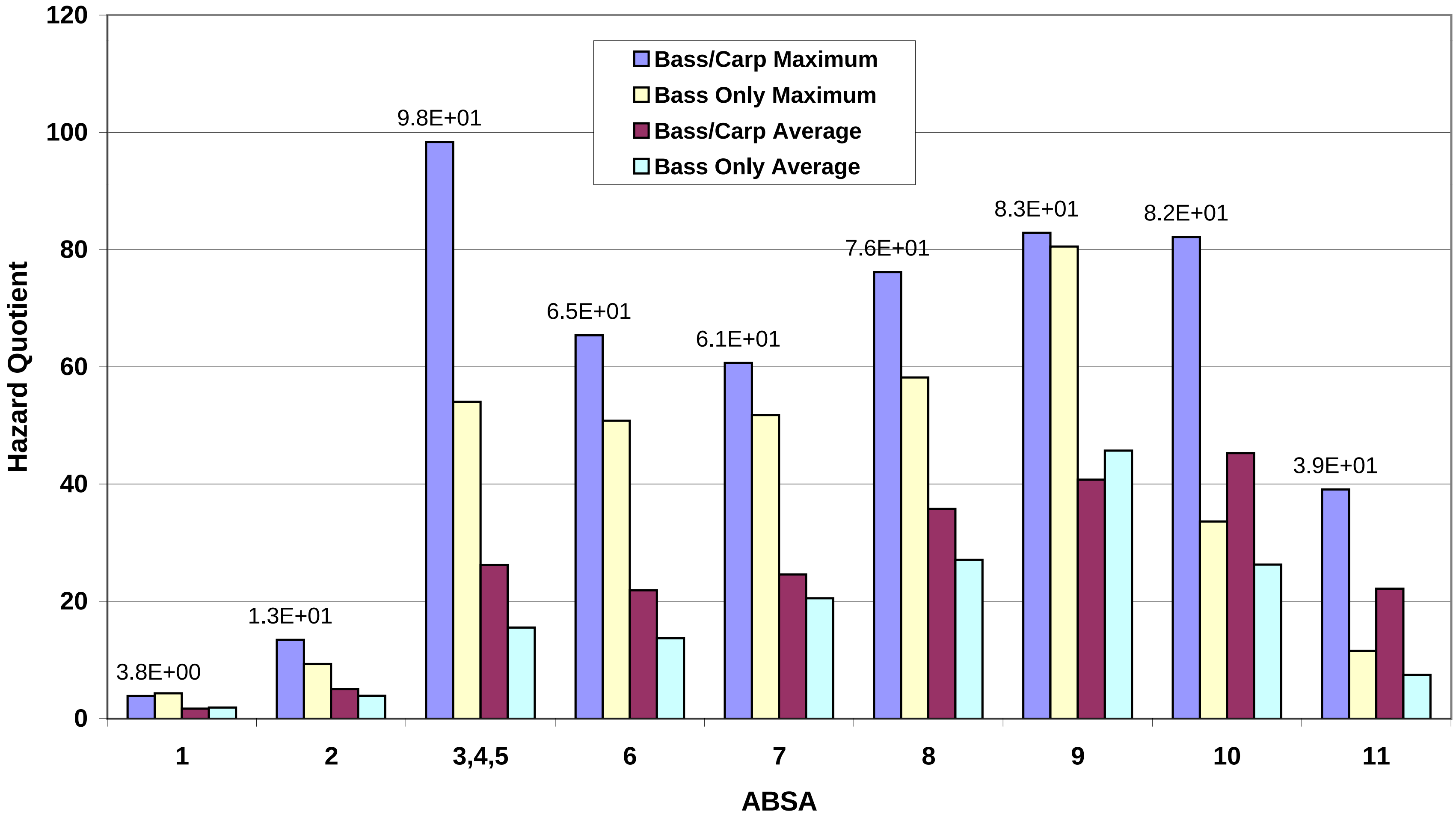


FIGURE 7-2

API/PC/KR SITE

Figures 7-1 and 7-2 also illustrate differences between average and maximum concentrations of PCB in fish fillets. Generally, these two values are substantially different, and risk management decisions based on one or the other value could result in different actions for the site. At present the small sample sizes (generally 11 fish of each species per ABSA) are not sufficient to provide long term estimates of average concentrations. Long-term averages would best reflect potential exposure for the scenarios addressed in this assessment. Currently, trends in fish tissue concentrations are being analyzed; these analyses may help address the issue of the applicability of risk estimates based on average and maximum concentrations.

The second most influential assumption for the fish ingestion scenario is the portion of fish caught from the contaminated source. For central tendency high-end sport anglers and subsistence anglers it was assumed that all of the fish ingested came from a particular ABSA. For high end sport anglers it was assumed half of the fish ingested came from a particular ABSA. Risks and hazards could be underestimated for those high-end anglers who catch all of their fish from different locations within the API/PC/KR site.

A reduction factor was used to account for the loss of PCBs when fish is cooked. This reduction factor did account for PCB losses during trimming fish and removing fat. Data reported in the Kalamazoo River Anglers Survey indicates that about 65 percent reported some trimming and skin removal prior to cooking.

The Michigan Sport Anglers Study also reported that between 44 and 84 percent of anglers did trim the fat from sport fish prior to cooking. For these reasons, use of a 50 percent overall reduction factor is believed to be appropriate for a large fraction of the population.

Residential exposure assumptions could overestimate risk for impoundment areas that are not readily accessible to residents. A recreational exposure scenario has been developed in an attempt to quantify exposure in hard-to-reach areas. However, application of the residential and recreational exposure scenarios is subject to a variety of considerations, including: (1) future risk is generally considered, and residential development may expand beyond current boundaries decreasing the area to which a recreational scenario would apply; and (2) the dynamic nature of the river system makes application of conservative assumptions appropriate. Periodic flooding may transport sediments from one area of an impoundment to another. Soils to which a recreational scenario is applied could be transported to an area where residential exposure is likely.

7.5 Risk Characterization and Calculation of RBCs

Assumptions are made using best professional judgment and the scientific literature on site risk assessments. In general, assumptions made throughout this risk assessment are conservative in that they tend to overestimate exposure and resultant risk rather than underestimate it. The overall risk to public health attributable to the site is an upper-bound probability of adverse health effects. True health effects may be lower. However, it should be noted that the individual errors from different sources might be propagated into larger errors by mathematical manipulation in the risk assessment.

Some quantification of variability associated with estimated RBC_{sed} can be developed using the results of the bootstrapping procedure discussed in Section 6.2. Bootstrapping was used to estimate both mean and upper and lower 95 percent confidence limits for BSAF. Mean BSAF estimates were used to calculate RBC_{sed} developed in Section 6.2. RBC_{sed} can also be calculated using upper and lower confidence limits to provide an indication of the range of RBC that could be considered in risk management of the site. Figures 7-3 and 7-4 illustrate these ranges for RBC_{sed} for cancer and noncancer (immunological) endpoint respectively.

Confidence intervals for RBC_{sed} based on cancer risk overlap for the Sport Angler - CTE and Sport Angler - High End, and for the Sport Angler - High End and Subsistence Angler (Figure 7-3). One might reasonably conclude that selection of a target clean-up level within the regions of overlap could be protective for many or most anglers in either category.

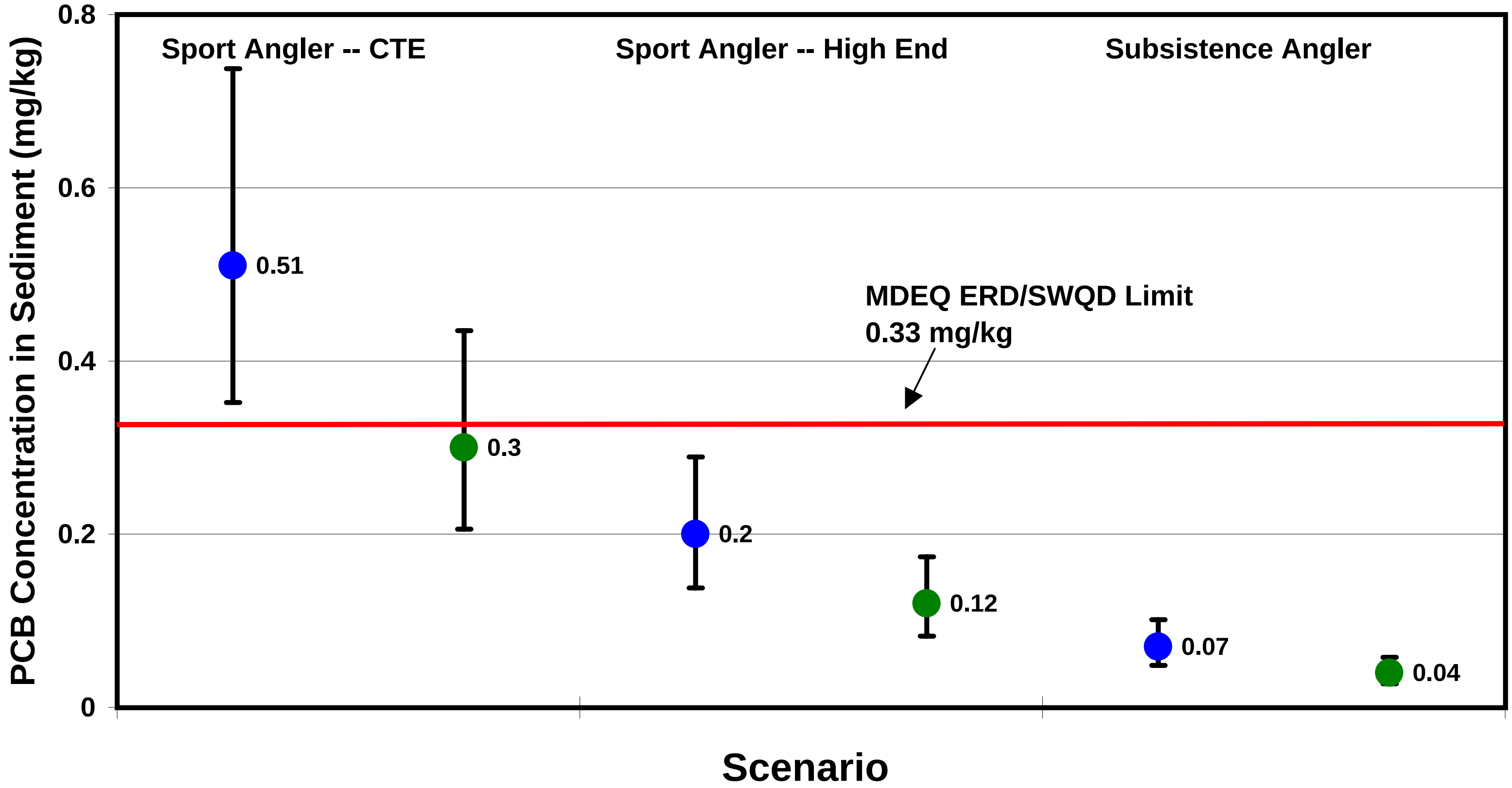
RBC_{sed} and associated confidence limits are generally lower than the MDEQ ERD/SWQD "detection limit" of 0.33 mg/kg for sediment. Actually, lower detection limits can be achieved in many samples; 0.33 is considered by the State to be a detection limit than can be reliably achieved in virtually all samples with PCB concentrations in the range of those commonly seen in riverine systems.

RBC_{sed} and associated confidence intervals are somewhat higher when based on noncancer (immunological) health concerns (Figure 7-4). Confidence intervals still overlap among scenarios. However, RBC_{sed} are higher than the MDEQ ERD/SWQD limit of 0.33 mg/kg in many cases. In fact, only ranges of RBC_{sed} for the subsistence angler are not higher than, or overlapping with this limit.

Variability in BSAF does suggest a range of estimated RBC_{sed} that represents possible protective clean-up targets for the API/PC/KR Site. One should note, however, that confidence intervals illustrated in Figures 7-3 and 7-4 do not consider many sources of uncertainty other than those associated with BSAF estimation. If these sources of uncertainty (many of which are discussed above) were evaluated quantitatively, confidence intervals about RBC_{sed} would widen. Widening of confidence intervals would increase overlap of possible clean-up targets among scenarios. One should not, therefore, assume that a target clean-up goal that exceeds the upper confidence limit for RBC_{sed} for any angler population would necessarily be nonprotective for all members of the population.

Risk assessment guidance (EPA 1989) stresses the importance of considering uncertainties in interpreting and applying results of any risk assessment. Thus, RBC_{sed} with associated confidence intervals as presented in Figures 7-3 and 7-4 may be the most appropriate for consideration in risk management for the site.

Confidence Intervals for Risk-Based Concentrations Based on Variability in BSAF
RBC_{sed} Based on Cancer Risk Target of 1 in 100,000



Note: RBC for Bass Only Consumption in Blue; RBC for Bass/Carp Consumption in Green

FIGURE 7-3

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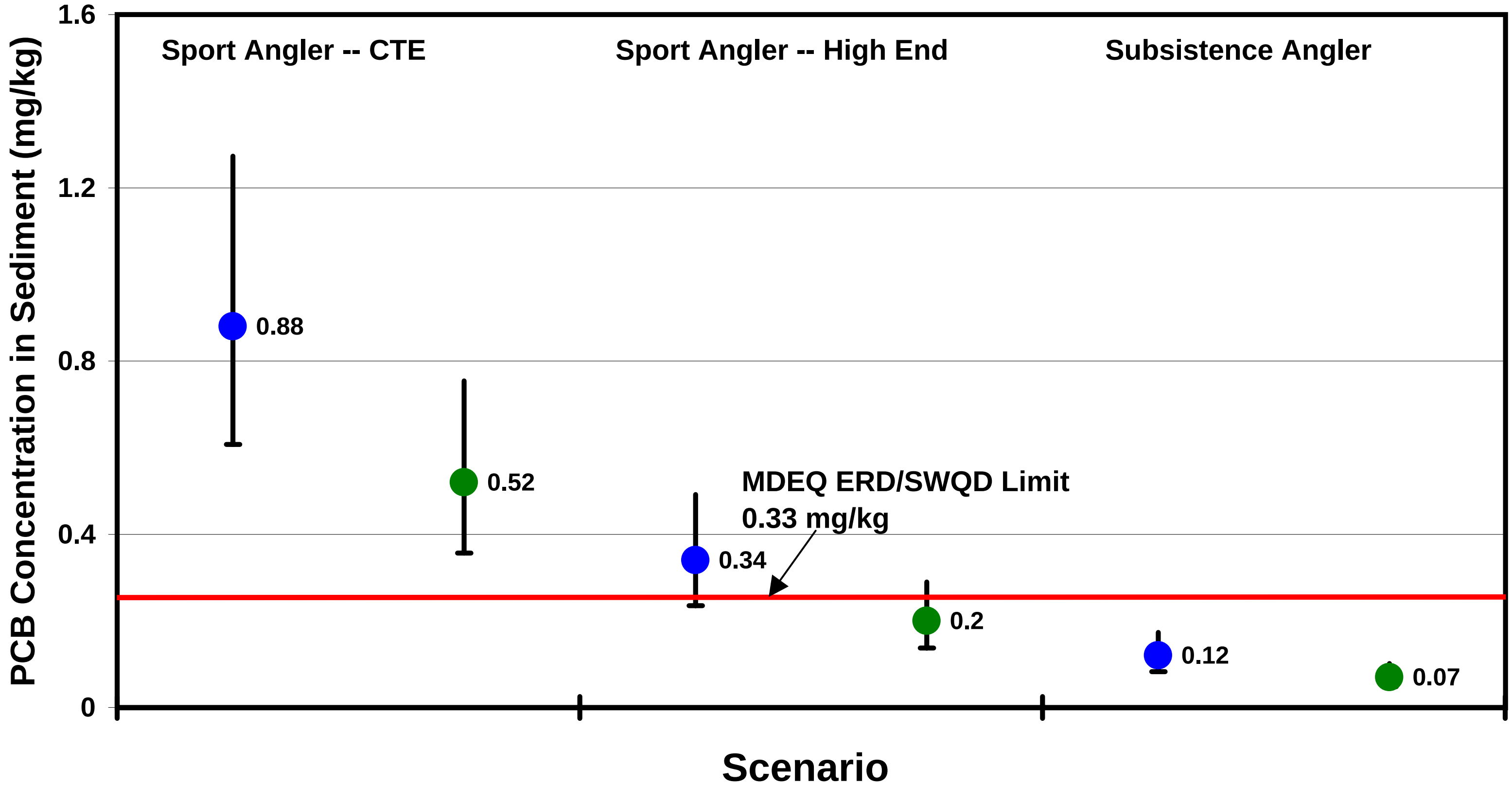
Confidence Intervals for Risk-Based Concentrations Based on Variability in BSAF
RBC_{sed} Based on Hazard Quotient Target of 1



Note: RBC for Bass Only Consumption in Blue; RBC for Bass/Carp Consumption in Green

FIGURE 7-4

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